UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: CERTAIN CONSOLIDATED ZOLEDRONIC ACID CASES	Consolidated Civil Action No. 12-03967 (SDW) (SCM) [Consolidated with Civil Action Nos. 12-cv-04393, 13-cv-01028, 13-cv-02379, 13-cv-4669, 13-cv-5125, 13-cv-6835, 13-cv-7914 and 14-cv-18411]
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. SAGENT PHARMACEUTICALS, INC., Defendant.	Civil Action No. 2:14-cv-07556-SDW-SCM

~~[PROPOSED]~~ STIPULATED ORDER

WHEREAS, Sagent Pharmaceuticals, Inc. ("Sagent") filed Abbreviated New Drug Application ("ANDA") No. 091493 for approval to market 4 mg / 5 mL zoledronic acid injection ("Sagent 4 mg / 5 mL ANDA Product"), which is a generic version of Novartis's ZOMETA® product;

WHEREAS, Plaintiff Novartis Pharmaceuticals Corporation ("Novartis") has asserted in this patent infringement suit that the filing of the Sagent 4 mg / 5 mL ANDA Product infringes U.S. Patent No. 8,324,189 ("the '189 patent") and that, upon approval, the commercial manufacture, use, sale, and offer for sale of the Sagent 4 mg / 5 mL ANDA Product will infringe the '189 patent (Civil Action No. 2:14-cv-07556-SDW-SCM ("this Action"));

WHEREAS, in Civil Action No. 12-3967-SDW-SCM ("the Consolidated Action"), Sagent and Novartis (the "Parties") are currently litigating the validity, enforceability, and infringement of the '189 patent with regard to, among other things, Sagent's distribution of a 4 mg / 5 mL zoledronic acid injection product under Actavis's ANDA No. 202472 ("Actavis 4 mg/ 5 mL ANDA Product"), and which is a generic version of Novartis's ZOMETA® product;

WHEREAS, the Sagent 4 mg / 5 mL ANDA Product and the Actavis 4 mg / 5 mL ANDA Product are not materially different with respect to the disputed issues in this Action and the Consolidated Action;

WHEREAS, Sagent asserts that the '189 patent is invalid and not infringed by the Sagent 4 mg / 5mL ANDA Product;

NOW, THEREFORE, in the interests of efficiency and the conservation of judicial and litigant resources, the Parties hereby stipulate and agree as follows:

1. Novartis asserts that the commercial manufacture, use, sale, and/or offer for sale of the Sagent 4 mg / 5 mL ANDA Product infringes claims 2, 9, and 14 of the '189 patent ("the Asserted Claims"), which are the same claims that Novartis has asserted with respect to the Actavis 4 mg / 5 mL ANDA Product in the Consolidated Action.

2. Sagent asserts that the commercial manufacture, use, sale, and/or offer for sale of the Sagent 4 mg / 5 mL ANDA Product does not infringe the Asserted Claims and that the Asserted Claims are invalid.

3. The Parties stipulate and agree to stay this Action until validity, enforceability, and infringement of the Asserted Claims as to the Actavis 4 mg / 5 mL ANDA Product have been finally resolved in the Consolidated Action by judgment or final otherwise appealable order of this Court ("Final Decision"). In the event that the Consolidated Action is otherwise resolved,

e.g., settlement, the Parties will meet and confer as to how to proceed in this Action. The Parties stipulate and Sagent agrees to accept service of the Summons and Complaint in this Action as of the date of entry in the Court docket of this Stipulated Order and the Parties stipulate and agree that Sagent's time to answer or otherwise respond to the Summons and Complaint in this Action is extended until 60 days after the Court lifts the stay in this Action, but in the event that the stay is not lifted, Sagent shall not be required to answer or otherwise respond to the Summons and Complaint in this Action.

4. The Parties stipulate and agree that resolution of validity, enforceability and infringement of the Asserted Claims in the Consolidated Action as to the Actavis 4 mg / 5 mL ANDA Product will bind the Parties in this Action as to the Sagent 4 mg / 5 mL ANDA Product.

5. In light of the fact neither willful infringement nor damages are at issue or will be tried in the liability phase of the Consolidated Action, upon entry of a Final Decision in the liability phase in the Consolidated Action, the Parties shall so notify this Court, request the stay be lifted, request that a judgment should be entered in this Action with respect to the Sagent 4 mg / 5 mL ANDA Product, and submit a joint status report regarding whether this Action should be consolidated into the Consolidated Action for purposes of determining damages and willful infringement, if any. For the avoidance of doubt, nothing in this order shall prohibit the Parties from consolidating this Action with the Consolidated Action before a Final Decision is appealed, or prevent the Parties from participating in any appeal.

6. In the event that a Final Decision as to the validity, enforceability or infringement of the Asserted Claims with respect to the Actavis 4 mg / 5 mL ANDA Product is vacated, modified, affirmed, or reversed prior to appeal, on appeal, or upon remand from an appeal, the

Parties agree that any such Final Decision (as vacated, modified, affirmed or reversed) shall be applied to the Sagent 4 mg / 5 mL ANDA Product in this Action.

7. For the avoidance of doubt, any decision in the Consolidated Action as to attorneys' fees, costs expenses or interest shall not be applied in this Action.

SO ORDERED this 10th day of June, 2015

Hon. Steven C. Mannion, U.S.M.J.

SO STIPULATED:

Dated: April 2, 2015

s/ William J. O'Shaughnessy

William J. O'Shaughnessy
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 639-2094
woshaughnessy@mccarter.com

s/ Marilyn Neiman
Marilyn Neiman
Cozen O'Connor
277 Park Avenue
New York, NY 10172
(212) 883-4900
mneiman@cozen.com

Attorneys for Sagent Pharmaceuticals, Inc.

OF COUNSEL:

Jane M. Love, Ph.D.
Robert Trenchard
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

Lisa J. Pirozzolo
Kevin S. Prussia
Sean K. Thompson
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109

Amanda L. Major
Tracey C. Allen
Rachel Weiner Cohen
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue, N.W.
Washington, DC 20006
(202) 663-6000

Attorneys for Novartis Pharmaceuticals Corporation, Novartis Corporation, and Novartis AG